

Message Text

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PAGE 01 STATE 193362
ORIGIN HEW-06

INFO OCT-01 ARA-14 ISO-00 OES-09 EB-08 COME-00 /038 R

DRAFTED BY DHEW/FDA: JRWEINROTH:VO:
APPROVED BY OES/ENP/EN: WJWALSH, III
DHEW/PHS/OASH/OIH: MKEFAUVER
ARA/CAR RSURBER(INFO)
ARA/AND/V:WSERGEANT(INFO)

-----033326 011519Z /53

P 011400Z AUG 78
FM SECSTATE WASHDC
TO AMEMBASSY KINGSTON PRIORITY
AMEMBASSY CARACAS PRIORITY

UNCLAS STATE 193362

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, JM, VE

SUBJECT: FDA INITIATED RECALL - NO EFFECTIVE NEW ANIMAL
DRUG APPLICATION RECALL V-129-8

1. FDA ADVISES OF THE FOLLOWING RECALL:

PRODUCT INVOLVED: ADRENAL CORTEX INJECTION, 10 AND 30 CC
VIALS, A PRESCRIPTION DRUG REPORTEDLY LABELED FOR VETERIN-
ARY USE ONLY.

2. PRODUCT IDENTIFICATION- PRODUCT IS UNDER ZIRIN
LABORATORIES INTERNATIONAL INC., HIALEAH, FLA. LABEL. 10
CC AND 30 CC VIALS OF ADRENAL CORTEX INJECTION, LABELED
FOR VETERINARY USE. ZIRIN LABORATORIES IS AN OWN LABEL
DISTRIBUTOR OF THIS PRODUCT. ALL LOTS ARE INVOLVED.

3. MANUFACTURER/RECALLING FIRM: ANTHONY PRODUCTS, EL MONTE
CA. DISTRIBUTOR/RECALLING FIRM: ZIRIN LABORATORIES
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INTERNATIONAL INC., 199 W. 24TH STREET, HIALEAH, FLA. 33010.

4. REASON FOR RECALL RECOMMENDATION: FIRM CONDUCTED A
RECALL IN U.S. AS A RESULT OF FDA REGULATORY LETTER DATED
1/9/78 STATING THE PRODUCT IS CONSIDERED TO BE A NEW DRUG
WITHOUT AN APPROVED NEW ANIMAL DRUG APPLICATION.

5. NO DEATHS OR INJURIES HAVE BEEN REPORTED. THE FIRM DID NOT RECALL FROM THE FOREIGN CONSIGNEES, STATING THAT PREVIOUS EXPERIENCE HAS SHOWN THAT THE FOREIGN ACCOUNTS WILL NOT RETURN THE PRODUCT.

6. THE FIRM CONTINUED TO EXPORT THE PRODUCT AFTER FDA ADVISED THEM THAT IT WAS ILLEGAL BY A SECOND LETTER DATED 2/15/78.

7. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO ADVISE THEM OF RECALL. POST IS TO INFORM CONSIGNEES THEY ARE TO CONTACT ZIRIN LABORATORIES INTERNATIONAL REGARDING DISPOSITION OF PRODUCT AND FOR ANSWERS TO ANY QUESTIONS THEY MAY HAVE.

8. FOREIGN CONSIGNEES AS FOLLOWS:

N. BAILEY, 16 GENGIC AVE., KINGSTON JAMAICA

D. STENNENT, 25 SANDY LANE, KINGSTON, JAMAICA

MS. LILIAN ROJAS, CALLE HUMOCARO QTZ CURADRE, EL MARAUEZ, ESTADO MIRANDO, CARACAS, VENEZULA

DENNIS SASSO, 8 EARLS COURT, 9 CORRIEME CRESCENT, 28 CALSTON DRIVE, KINGSTON, JAMAICA
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BURKE, KINGSTON JAMAICA

RUDOLPH EDWARD, 16 CROSS ROADS, KINGSTON, JAMAICA

REN GONZALES, 46 EVELYN CRESCENT, KINGSTON JAMAICA

L. HYE, 2 G HIGHLAND DRIVE, KINGSTON, JAMAICA VANCE

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Message Attributes

Automatic Decaptioning: X
Capture Date: 01 jan 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: ANIMALS, DRUGS
Control Number: n/a
Copy: SINGLE
Draft Date: 01 aug 1978
Decaption Date: 01 jan 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 jan 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1978STATE193362
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH:VO:
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D780314-0925
Format: TEL
From: SECSTATE WASHDC
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1978/newtext/t197808111/aaaadppn.tel
Line Count: 102
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: bb1d6b59-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 2
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: 78 KINSHASA 07942, 78 STATE 184549
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 24 jun 2005
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 1575933
Secure: OPEN
Status: NATIVE
Subject: MSG DESIGNATED VEHICLES
TAGS: ASEC, OGEN, ETRD, EIND, TBIO, JM, VE
To: KINSHASA BRAZZAVILLE MULTIPLE
Type: TE
vdkgvwkey: odbc://SAS/SAS.dbo.SAS_Docs/bb1d6b59-c288-dd11-92da-001cc4696bcc
Review Markings:
Sheryl P. Walter
Declassified/Released
US Department of State
EO Systematic Review
20 Mar 2014
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